

REMARKS

Claims 1-8 and 14-20 are pending and under consideration. No amendments to the claims have been made. Certain amendments were made to the specification to enhance readability of the application and correct typographical errors. These amendments do not add new matter.

Information Disclosure Statement:

The Examiner indicated that the application, as filed on October 16, 2001, failed to include legible copies of the documents listed on the information disclosure statement ("IDS"). Applicants submit with this response a clean copy of each reference listed on the IDS. Because the Examiner was not specific as to which references are needed, Applicants submit copies of all references listed. If the Examiner determines that the IDS still does not comply, please call the undersigned to discuss in more detail what is needed to bring it into compliance.

Amendments to the Specification:

Certain editorial changes were made to the specification to enhance readability of the application. These amendments do not add new matter.

Claim Interpretation:

The Examiner found that the specification lacked any structural limitations on the claimed term "cartridges". Accordingly, the Examiner indicated that the term "cartridges" would be interpreted broadly to include any component which can achieve the claimed function whatsoever. Applicants respectfully disagree with the Examiner's characterization of the term "cartridges."

Applicants assert that "cartridges" refer to separate structures that fit into an instrument and can be removed from that instrument. Support for this interpretation can be found, e.g., in the specification at paragraph [027], lines 1 to 6. Thus, a photodetector is not a "cartridge" according to the present invention because it cannot be removed from an instrument. In addition, Applicants point out that the claims do not use the term "cartridge" alone, but rather recite either "companion cartridge" and/or "sensing cartridge". These terms are clearly defined in paragraph [006], lines 7 to 17.

Rejections Under 35 U.S.C. § 102(b):

In the outstanding Office Action, the Examiner rejected claims 1-8 and 14-20 under 35 U.S.C. § 102(b). Applicants respectfully traverse this rejection. Claims 1-8 and 14-20 are pending and under consideration.

Rejection Under 35 U.S.C. § 102(b): Lipshutz

The Examiner rejected claims 1-8 and 14-20 under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Pat. No. 5,856,174 to Lipshutz et al., ("Lipshutz"). Office Action at pages 3 to 4. Applicants respectfully traverse.

The Examiner construed a "reader device" in Lipshutz as a "sensing cartridge", as that term is used in the present application. (See Office Action at page 3, referring to Lipshutz, col. 11, lines 48-52). However, Lipshutz teaches that a "reader device" scans and obtains data from the miniaturized diagnostic device. (See Lipshutz, col. 4, lines 18-19). Thus, the "reader device" taught by Lipshutz does not conduct chemical analysis, but merely receives data from analytical devices.

That teaching is inconsistent with the definition of "sensing cartridge" as "a cartridge which can conduct chemical analysis on several parameters of a body fluid sample, and comprises sufficient reagent and calibration fluids for a majority of the desired types of chemical analysis." (See paragraph [006], lines 11-14). Nowhere does Lipshutz teach either that the "reader device" can conduct chemical analyses or that the "reader device" comprises reagent or calibration fluids. Indeed, as stated above, Lipshutz teaches that a "reader device" merely scans and obtains data from the miniaturized diagnostic device, and therefore does not conduct chemical analysis on its own. (See Lipshutz, col. 4, lines 18-19). Accordingly, Applicants respectfully submit that the "reader device" disclosed by Lipshutz cannot be fairly construed as a "sensing cartridge" as defined by the present application.

Moreover, Lipshutz does not disclose that the "cartridge," as construed by the Examiner, can be removable from an instrument. As discussed above, the term "cartridges" refer to separate structures that can fit into and be removed from an instrument. Although Lipshutz teaches that it may be desirable in some cases to incorporate the reader device into the diagnostic device, nowhere does Lipshutz teach that the reader device can be removed from the diagnostic device. Accordingly, Applicants submit that Lipshutz does not contain each and every element of claim 1.

Regarding claims 19 and 20, the Examiner cites nearly two columns of text (i.e., col. 26, line 43 to col. 28, line 24) for the proposition that Lipshutz teaches a removable cartridge. Office Action at page 4. It is unclear to Applicants what the Examiner construes as a “sensing cartridge” or a “companion cartridge” within this citation. Moreover, nowhere in this citation does Lipshutz teach a removable “cartridge.” The closest that the art teaches is a reusable base unit that does not include a recitation that the base unit is removable.

Since claims 1, 14, and 19 recite, among other things, “a companion cartridge” in contact with a “sensing cartridge,” the arguments above apply to all of these claims. For at least these reasons, Applicants respectfully submit that Lipshutz does not anticipate claims 1, 14, and 19, and that these claims are patentable over Lipshutz.

Claims 2-8 ultimately depend from claim 1, claims 15-18 depend from claim 14, and claim 20 depends from claim 19. Thus, these claims are also not anticipated by Lipshutz.

Rejection Under 35 U.S.C. § 102(b): Sakata

The Examiner rejected claims 1-8, 14-17, 19, and 20 under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Pat. No. 5,296,378 to Sakata et al., (“Sakata”). Office Action at pages 4 to 5. Applicants respectfully traverse.

The Examiner states that “the flow cytometer column is interpreted as the ‘companion cartridge’ while the laser detection and photomultiplier tube are interpreted as the ‘sensing cartridge’.” Office Action at page 4. Sakata teaches that the “laser detection and photomultiplier tube” consist of an argon ion laser that irradiates leukocytes in a blood sample causing them to fluoresce, which is, in turn, detected by a photomultiplier tube. (See Sakata, col. 12, lines 10-39). Thus, the laser is a device which generates energy in the form of light and the photomultiplier tube is a device which detects emitted light.

That teaching is inconsistent with the definition of “sensing cartridge” as “a cartridge which can conduct chemical analysis on several parameters of a body fluid sample, and comprises sufficient reagent and calibration fluids for a majority of the desired types of chemical analysis.” (See paragraph [006], lines 11-14). Nowhere does Sakata teach that the “laser detection and photomultiplier tube” comprises reagent or calibration fluids. Accordingly, Applicants respectfully submit that the “laser

detection and photomultiplier tube” disclosed by Sakata cannot be fairly construed as a “sensing cartridge” as defined by the present application.

Moreover, Sakata does not disclose that the “cartridge,” as construed by the examiner, can be removable from an instrument. As discussed above, the term “cartridges” refer to separate structures that can fit into and be removed from an instrument. The Examiner stated that “the flow cell can be removed from the flow cytometer, inherently...,” but nowhere does Sakata teach that the flow cell can be removed from the diagnostic device. Accordingly, Applicants submit that Sakata does not contain each and every element of claim 1.

Since claims 1, 14, and 19 recite, among other things, “a companion cartridge” in contact with a “sensing cartridge,” the arguments above apply to all of these claims. For at least these reasons, Applicants respectfully submit that Sakata does not anticipate claims 1, 14, and 19, and that these claims are patentable over Sakata.

Claims 2-8 ultimately depend from claim 1, claims 15-18 depend from claim 14, and claim 20 depends from claim 19. Thus, these claims are also not anticipated by Sakata.

Rejection Under 35 U.S.C. § 102(b): Andresen

The Examiner rejected claims 1-8, 14, 15, and 18-20 under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Pat. No. 6,126,804 to Andresen et al., (“Andresen”). Office Action at pages 5 to 6. Applicants respectfully traverse.

The Examiner’s terse statement with respect to this reference provides little guidance to Applicants. In particular, the Examiner stated that Andresen teaches a “cartridge” and refers broadly to figures 1 and 2. Office Action at page 5. However, Applicants cannot determine what the Examiner construes as a “sensing cartridge” or a “companion cartridge” with absolute certainty. The Examiner’s construction appears to be that Fig. 1 (the single channel integrated PCR/CE instrument) is a “companion cartridge” and that item 24 (the photodetector) is a “sensing cartridge”. Applicants will proceed with that understanding.

Andresen does not disclose that the “cartridge,” as construed by the examiner, can be removable from an instrument. As discussed above, the term “cartridges” refer to separate structures that can fit into and be removed from an instrument. The Examiner stated that “Andresen teaches a removable cartridge (see figure 1)...” Office Action at page 6. But Figure 1 of Andresen does not teach that either the

photodetector or the single channel integrated PCR/CE instrument can be removed from an instrument. Indeed, nowhere does Andresen teach that these items are removable. Accordingly, Applicants submit that Andresen does not contain each and every element of claims 1, 14, and 19.

The Examiner stated that “Andresen teaches attachment of the column to a sensor which detects the amplified DNA (see column 4, lines 1-8).” With this statement, the Examiner appears to construe a “photodetector” in Andresen as a “sensing cartridge,” as that term is used in the present application. However, Andresen teaches that a “photodetector,” such as a photodiode, is used to detect light generated by the machine as it passes through DNA fragments. (See Andresen, col. 4, lines 1-8; and col. 5 lines 52-53). That teaching is inconsistent with the definition of “sensing cartridge” as “a cartridge which can conduct chemical analysis on several parameters of a body fluid sample, and comprises sufficient reagent and calibration fluids for a majority of the desired types of chemical analysis.” (See paragraph [006], lines 11-14). Nowhere does Andresen teach that the “photodetector” comprises reagent or calibration fluids. Accordingly, Applicants respectfully submit that the “photodetector” disclosed by Andresen cannot be fairly construed as a “sensing cartridge” as defined by the present application.

Since claims 1, 14, and 19 recite, among other things, “a companion cartridge” in contact with a “sensing cartridge,” the arguments above apply to all of these claims. For at least these reasons, Applicants respectfully submit that Andresen does not anticipate claims 1, 14, and 19, and that these claims are patentable over Andresen.

Claims 2-8 ultimately depend from claim 1, claims 15-18 depend from claim 14, and claim 20 depends from claim 19. Thus, these claims are also not anticipated by Andresen.

Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: December 23, 2003

By: 

John Y. Pfeifer
Reg. No. 52,120

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Signed: 

Linda Phillips